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DECLARATION OF DR. EDMUND ELDER 7285-v1/1003.0050

THIS DOCUMENT RELATES TO:

**ALL ACTIONS** 

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

IN RE TRICOR DIRECT PURCHASER
ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS

IN RE TRICOR INDIRECT PURCHASER
ANTITRUST LITIGATION

C.A. No. 05-340 (SLR)

(Consolidated)

REDACTED

PUBLIC INSPECTION VERSION

C.A. No. 05-360 (SLR)

(Consolidated)

#### DECLARATION OF DR. EDMUND ELDER

- I, Edmund J. Elder, Jr., Ph.D., submit this Declaration pursuant to 28 U.S.C. § 1746 and declare as follows:
- 1. I have personal knowledge of facts stated in this Declaration, and if called upon as a witness, could and would testify competently thereto.
- 2. I have been retained as an expert in the above-captioned action on behalf of plaintiffs Louisiana Wholesale Drug Co., Inc., Rochester Drug Co-Operative, Co., Meijer Inc., and Meijer Distribution, Inc. (collectively, the "Direct Purchaser Class Plaintiffs"), plaintiffs CVS pharmacy, Inc., Rite Aid Corporation, and Rite Aid Hdqtrs. Corp. (collectively, the "CVS and Rite Aid Plaintiffs"), and plaintiffs Walgreen Co.,

Eckerd Corporation, The Kroger Co., Maxi Drug, Inc. d/b/a/ Brooks Pharmacy, Albertson's, Inc., Safeway, Inc., American Sales Co., Inc., and Hy-Vee, Inc. (collectively, the "Walgreen Plaintiffs") in this antitrust action brought against defendants Abbott Laboratories ("Abbott") and Fournier Industrie et Santé and Laboratories Fournier S.A. (collectively, "Fournier").

- 3. I received a B.S. in Pharmacy and a Ph.D. in Pharmaceutical Sciences from the Medical University of South Carolina in 1985 and 1989, respectively. My curriculum vitae is attached as Exhibit A to this Declaration.
- 4. On December 14, 2006, I submitted an expert report in this case entitled "Expert Report of Dr. Edmund Elder." The Expert Report of Dr. Edmund Elder is attached as Exhibit B to this Declaration and is hereby incorporated by reference into this Declaration.
- 5. On August 2, 2007, I submitted another expert report in this case entitled "Expert Rebuttal Report of Dr. Edmund Elder." The Expert Rebuttal Report of Dr. Edmund Elder is attached as Exhibit C to this Declaration and is hereby incorporated by reference into this Declaration.

I declare under penalty of perjury that the foregoing is true and correct.

Executed June 2, 2008

Edmund J. Elder

## **EXHIBIT A**

#### Edmund J. Elder, Jr., R.Ph., Ph.D.

(Ed)

7401 North Pass Madison, WI 53719 (608) 497-0117

ed\_elder@alumni.musc.edu

University of Wisconsin-Madison School of Pharmacy Rennebohm Hall 777 Highland Avenue Madison, WI 53705-2222 (608) 890-1198 eelder@pharmacy.wisc.edu

#### **EDUCATION:**

Medical University of South Carolina, Charleston, SC Ph. D., Pharmaceutical Sciences; November 1989 B.S., Pharmacy; May 1985

Clemson University, Clemson, SC Pre-Professional Studies, Pre-Pharmacy 1980-1982

#### EMPLOYMENT:

#### University of Wisconsin-Madison

School of Pharmacy

Associate Director, Zeeh Pharmaceutical Experiment Station

#### Current Responsibilities

- Key scientific leader for the Station in providing pre-formulation and formulation services for UW and non-UW clients
- Provide pharmaceutics expertise to support pharmaceutical and biopharmaceutical development collaborations across campus and for external clients
- Advise and mentor Station staff
- Apply project management and business development experience to enhance Station operational effectiveness
- Share knowledge and expertise through Station participation in and sponsorship of educational
  programs addressing the process and science of drug development in collaboration with UWMadison, School of Pharmacy, Extension Services in Pharmacy (continuing education division)

#### The Dow Chemical Company, Midland MI

Dowpharma<sup>sм</sup>

Global Parmaceutical Development Director / Applications Development Leader, April 2004 – April 2006

Pharmaceutical Technologies Group

Pharmaceutics Director / Technical Leader, August 2000 - April 2004

#### Prior Responsibilities

- Co-leader (with commercial leader), new business development: BioAqueous<sup>SM</sup> Solubilization Services
- Oversight of multi-departmental technical activities for development of a drug delivery service offering
  including interfacial sciences, engineering, analytical, toxicology, intellectual property/legal, licensing,
  manufacturing, project management, technical service and QA/regulatory
- Lead external technology development collaborations and alliances including a multi-year university research program
- Represent technical program during client interactions for commercial development activities
- Provide pharmaceutics expertise for various emerging corporate growth opportunities
- Serve as a mentor for potential future leadership staff through formal corporate program

<sup>&</sup>lt;sup>SM</sup> Service Mark of The Dow Chemical Company

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Ed Elder, Jr.

#### Glaxo / Glaxo Wellcome (now GlaxoSmithKline), Research Triangle Park, NC

Pharmaceutical Sciences

Sr. Group Leader, Formulation and Process Development, November 1997 to August 2000 Group Leader, Formulation Development, February 1997 to November 1997

Process Science and Technology

Research Leader, Liquids Process Development, September 1995 to February 1997 Research Leader, Pharmaceutical Technology Development, July 1994 to August 1995 Research Investigator, May 1992 to June 1994 Senior Scientist, September 1989 to April 1992

#### Previous Experience

- Management: Group of ten formulation and process development scientists, covering all dosage forms, mentoring of new CMC team leaders, department management team and division leadership
- Project Management: Chemistry manufacturing & controls (CMC) matrix team leader
  - Responsible for oversight of all cross-functional CMC activities for multiple development programs
  - Represented CMC interests on international product development teams
  - Lead technology transfer and manufacturing site new product implementation teams.
  - Key R&D contact for FDA pre-approval inspections of domestic and foreign contract manufacturing
- Formulation and process development, optimization and scale-up using statistical experimental design
- Primary interface with external development and manufacturing sites for new dosage form technologies including: soft gelatin capsules, effervescent products, and sterile products blow-fillseal technology

#### Medical University of South Carolina, Charleston, SC

Department of Pharmaceutical Sciences, Pharmaceutical Development Center (now part of AAI) Research Pharmacist and Teaching Assistant, August 1985 to September 1989

#### Burroughs Wellcome Company, Greenville, NC

Pharmaceutical Research and Development Laboratory

Pharmaceutics Graduate Student Fellow, June 1986 to August 1986

#### Family Pharmaceuticals of America, Inc., Mt. Pleasant, SC

Mail-service and retail pharmacy, acquired by Medi-Mail, Inc. in 1994, subsequently acquired by Bergen Brunswig Corporation, now AmerisourceBergen Corporation

Minor Partner, subchapter-S corporation, January 1987 to June 1995

Part-time Pharmacist, June 1985 to August 1989

Pharmacy Intern, May 1983 to June 1985

#### PROFESSIONAL ACHIEVEMENTS:

44 Scientific Presentations (9 invited)

7 Publications and 1 book contribution

The Visiting Scientist Program for Schools of Pharmacy and Pharmaceutical Scientists

Presented lectures/seminars at 14 schools/colleges of Pharmacy, 1993-2005

#### **Guest Lecturer**

- University of Texas at Austin, College of Pharmacy, 2001-2005
- Michigan State University, ISPE Student Chapter, 2004
- Medical University of South Carolina, Department of Pharmaceutical Sciences, 1991-1999
- Virginia Commonwealth University/Medical College of Virginia, School of Pharmacy, 1997

Faculty, The Toxicology Forum 29th Annual Winter Meeting, Nanoscale Materials and Public Health. Washington, DC, 2004

Faculty, AAPS 30th Annual Arden House Conference: Particle Formation and Particle Coating for Pharmaceutical Delivery Systems, 1995

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Ed Elder, Jr.

#### LICENSURE:

South Carolina Pharmacist License

#### PROFESSIONAL ACTIVITIES/MEMBERSHIPS/AWARDS

American Association of Pharmaceutical Scientists (AAPS), member 1990 – present (student member 1987–1989)

Annual Meeting paper screener (PT Section), 2006, 1994 – 2000

Co-Chair 2004 Annual Meeting Short Course, Particle Engineering Technologies: Theory and Practice

Moderator (PT Podium Session: Pharmaceutical Processing and Scale-up), Tenth Annual Meeting and Exposition, Miami Beach, FL, 1995

Planning Committee and Moderator (PT Section), 1995 Southeast Regional Meeting, RTP, NC AAPS Special Appreciation Award, 1994 – Co-Chair, 1994 Southeast Regional Meeting, Durham, NC

Drug Development and Industrial Pharmacy

Editorial Advisory Board, 2006 - present

Journal Article Reviewer, 2000 - present

Journal of Biomedical Nanotechnology

Journal Article Reviewer - Special Issue on "Nanotechnology in Advanced Drug Delivery", 2006

ISPE Award for Outstanding Service to the Technology Transfer Task Team, November 2003 (book contributions)

The Dow Chemical Company, Special Recognition Award, December 2002 (creation and launch of BioAqueous<sup>SM</sup> Solubilization Services)

European Federation for Pharmaceutical Sciences (EUFEPS), member 2003 - present

Controlled Release Society (CRS) - member 2001 - present

Sigma Xi, The Scientific Research Society, member 1988 - present

Medical University of South Carolina (MUSC)

Lifetime Member, MUSC Alumni Association

Alumni Association Planning Committee, College of Pharmacy, Class of 1985, Reunion 2000

Chairman, College of Graduate Studies Annual Fund, 1998-1999

Alumni Association Student Research Day Judge, 1996-1998

The Rho Chi Society (Pharmacy Honorary), 1987

Roche Pharmacy Communications Award, 1985

McKesson Presidential Award, 1985

Eagle Scout, Troop 1429 Charleroi, PA, July 26, 1976

Lifetime Member, National Eagle Scout Association

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Ed Elder, Jr.

#### **PUBLICATIONS**

- EJ Elder, JC Evans, BD Scherzer, GB Kupperblatt, SA Saghir, DA Markham, and JE Hitt, Preparation, Characterization, and Scale-up of Ketoconazole with Enhanced Dissolution and Bioavailability, Drug Development and Industrial Pharmacy, accepted Aug 2006, publication pending.
- EJ Elder, JE Hitt, TL Rogers, CJ Tucker, SA Saghir, S Svenson, and JC Evans, Particle Engineering of Poorly Water Soluble Drugs by Controlled Precipitation in Polymeric Drug Delivery Volume II -Polymeric Matrices and Drug Particle Engineering, Svenson, S., (Ed.), ACS Symposium Series, Vol. 924, American Chemical Society, Washington, DC, March 2006.
- JC Evans, BD Scherzer, CD Tocco, GB Kupperblatt, JN Becker, DL Wilson, SA Saghir, and EJ Elder. Preparation of Nanostructured Particles of Poorly Water Soluble Drugs via a Novel Ultra-Rapid Freezing Technology in Polymeric Drug Delivery Volume II - Polymeric Matrices and Drug Particle Engineering, Svenson, S., (Ed.), ACS Symposium Series, Vol. 924, American Chemical Society, Washington, DC, March 2006.
- TL Rogers, IB Gillespie, JE Hitt, KL Fransen, CA Crowl, CJ Tucker, GB Kupperblatt, JN Becker, DL Wilson, C Todd, CF Broomall, JC Evans, and EJ Elder, Development and Characterization of a Scalable Controlled Precipitation Process to Enhance the Dissolution of Poorly Water-Soluble Drugs, Pharmaceutical Research, 21(11), 2048-2057, 2004.
- RD Connors and EJ Elder, Using a Portfolio of Particle Growth Technologies to Enable Delivery of Drugs With Poor Water Solubility, Drug Delivery Technology, 4(8), 78-83, 2004.
- EJ Elder, JE Hitt, TL Rogers, CJ Tucker, SA Saghir, S Svenson, and JC Evans, Particle Engineering of Poorly Water Soluble Drugs by Controlled Precipitation, Polymeric Materials Science and Engineering, Vol. 89, p 741 (2003)
- JC Evans, BD Scherzer, CD Tocco, GB Kupperblatt, JN Becker, DL Wilson, SA Saghir, and EJ Elder, Preparation of nanostructured particles of poorly water soluble drugs via a novel ultra-rapid freezing technology, Polymeric Materials Science and Engineering, Vol. 89, p 742 (2003)
- EJ Elder (contributor), Dosage Forms (Clinical Supplies and Commercial Product): APIs, Excipients and Raw Materials, Chapter 5.3 in Technology Transfer (ISPE Good Practice Guide), ISPE, Tampa, FL, 2003.

# **EXHIBITS B-C REDACTED**